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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,978	04/25/2001	Steven Ball	BET-00/1188	4958

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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

14

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/719,978

Applicant(s)

BALL, STEVEN

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-27 is/are rejected.
- 7) ☒ Claim(s) 28-29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-18 have been cancelled and Claims 19-29 newly added.

Applicant's arguments will be addressed to the extent that they read upon newly added Claims 19-29.

Rejection of the Claims under 35 U.S.C. 102(b) is withdrawn in view of Applicant's amendments.

#### ***Claim Rejections - 35 USC § 112***

Claims 19-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 10/07/02. Applicant's arguments filed 4/07/03 have been considered but are not deemed persuasive.

Applicant asserts that the Examiner alleged that the present disclosure fails to support claims directed to fragments of SEQ ID NO: 1 that encode for a protein having  $\alpha$ -1,4 glucanotransferase activity (response page 4, lines 12-15) and that one of skill in that art could readily determine, as shown in Example 4, whether or not a polypeptide encoded by a fragment of SEQ ID NO: 1 has the activity of the required invention (response page 4 line 15 to page 5 line 3). Claims 19-20 are drawn to a multitude of nucleic acid sequences from a multitude of sources which somehow increase or decrease enzyme activity. Since the claims are also drawn to

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an isolated polynucleotide sequence from any source that encodes any  $\alpha$ -1,4 glucanotransferase or any isolated polynucleotide sequence encoding any  $\alpha$ -1,4 glucanotransferase that has 75% sequence identity to SEQ ID NO: 1 or hybridizes to SEQ ID NO: 1 under conditions of unspecified stringency and because Applicant describes only SEQ ID NO: 1 encoding SEQ ID NO: 2, Applicant has not described the invention. Further, determining the encoded function of a fragment of a polynucleotide does not describe what it is. Furthermore, because the isolated DNA sequences are not described, methods of using said sequences are not described as well. See Written Description Guidelines, Federal Register Vol. 66 No. 4, Friday January 5, 2001 "Notices", pages 1099-1111.

Claims 19-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official actions mailed 10/07/02. Applicant's arguments filed 4/07/03 have been considered but are not deemed persuasive.

Applicant asserts that the enablement rejection contends that the present application would not provide sufficient guidance to obtain a plant with amylopectin enriched with starch chains of less than 6 glucose residues and that two unpersuasive documents were relied upon in making this rejection. Applicant is incorrect. The rejection is also directed to methods that do not recite a means of modifying enzyme activity directly, as exemplified in present Claims 19-20 and 22-23.

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Applicant asserts that the Willmitzer reference actually discloses a higher rate of success of transgenesis than the Office Action contends (response page 5 and 6) on page 26, last paragraph (probably page 36); page 37, fourth paragraph; and page 38, second paragraph. Pages 36 and 37 only refer to an increase in the total starch content of transgenic plants and page 38 only refers to an increase of amylose content in a mutant, not a transgenic, as Applicant has asserted in their argument.

Applicant further asserts that because Willmitzer concludes, on page 38 fifth paragraph, that the presence of an unknown isoform may explain the absence of a modified phenotype in antisense plants, the reference does not impinge upon their claimed method (response page 6, lines 4-11). Clearly, Willmitzer's speculation about an unknown isoform indicates the multifaceted nature of unpredictability in the art of starch modification using transgenic antisense constructs and bears directly upon Applicant's claimed method of starch modification in non-exemplified plants using a heterologous DNA.

Applicant asserts that Kossman and Willmitzer refer to the same experiment and that Kossman also fails to demonstrate that the instant invention does not satisfy the requirements of 35 U.S.C. 112 first paragraph (response page 6 lines 15-26).

Applicant asserts that the art does teach successful modification of starch by transgenesis (response page 6 line 27 to page 7 line 7). Applicant is arguing limitations that are not in the claims. Although the cited references argue for either increased starch content or altered amylose/amylopectin ratios in plants by means of plant transformation with particular defined genes, there is nothing to suggest that any of the modifications of the cited references resulted in plants that comprise enrichment in amylopectin chains of at least 9 glucose residues or less than

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6 glucose chains set forth in method Claims 19-23. Furthermore, the references do not teach the <sup>proteins</sup> use of sequence variants or methods of altering enzyme activity using genes or unrelated to the gene encoding the target enzyme. ^

Applicant asserts that the demonstration of the amylopectin modifying activity of the disclosed glucanotransferase enzyme from *Chlamydomonas* in Examples 3-5 is adequate disclosure of a method for producing a transgenic plant (response page 7 lines 8-16). The prior art does not support starch modification as claimed by Applicant using a polynucleotide encoding a glucanotransferase enzyme.

Applicant asserts that the claims are no longer indefinite (response page 7). The newly submitted Claims are indefinite.

Claim 21 and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

At Claim 21, line 7, an --and-- should follow the semicolon.

At Claim 24, line 2, "an  $\alpha$ -1,4 glucanotransferase" is indefinite. It is unclear whether the  $\alpha$ -1,4 glucanotransferase is the native or expressed from a transgene.

### ***Claim Rejections - 35 USC § 101***

Claims 26-27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The DNA of Claims 26-27, since it has not been isolated by the hand of man reads as a product of nature, thus falling outside the five classes of patentable subject matter. The DNA molecule, as claimed, has the same characteristics and utility as those

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found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claims 19-27 are rejected.

Claims 28-29 are objected to because they depend from rejected Claims 26-27.

The Claims are deemed free of the prior art given the failure of the art to teach or reasonably suggest plants having either increased or decreased levels of expression of an  $\alpha$ -1,4 glucanotransferase or a polynucleotide sequence of SEQ ID NO: 1 or a polynucleotide sequence having 70% sequence identity to SEQ ID NO: 1.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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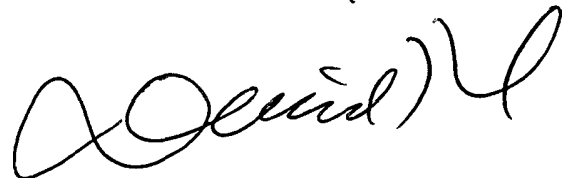
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Russell Kallis Ph.D.  
June 12, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and title.